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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,623	09/19/2001	J. Christopher Flaherty	59249-020 (INSL-117)	1126

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INSULET CORPORATION

9 Oak Park Drive
Bedford, MA 01730

EXAMINER

HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,623

Applicant(s)

FLAHÉRTY, J. CHRISTOPHER

Examiner

Michael J. Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 9-14, 16, 17, 19-22 and 24-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 8, 15, 18 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) .
Paper No(s)/Mail Date 1/22/04 4/26/04, 11/21/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 12/13/01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. There is no copy of the foreign patent documents nor the other documents (non-patent literature) listed on the IDS. The U.S. patents documents have been obtained through a data base and have been considered. Applicant is requested to resubmit the foreign patent documents nor the other documents (non-patent literature) so they can be considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: those required to have the plunger move only in a single direction on the lead screw. Applicant's amendment reciting the lead screw does not supply the

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structure that limits the plunger to moving only in a single direction. A lead screw does not limit movement in only one direction by itself. There remains omitted elements. If Applicant is not trying to claim movement in only a single direction then Applicant should recite that the plunger "is capable of" moving in a single direction. This would clarify that although two way movement can occur, the claim is focused on the capability of one way movement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by WILEY (US Patent No. 6,244,776). Wiley discloses a device for delivering fluid including an exit port adapted to connect to a patient access tool by threads on the exit port, a reservoir with end walls, a threaded lead screw 86, plunger 84, and dispenser 87 for rotating the lead screw (col. 4, ll. 56-65). The lead screw is directly coupled to the proximal end wall of the reservoir. See fig. 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 8, 15, 18, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitney et al. (US Patent No. 4,342,311). Whitney discloses a device for delivering fluids to a patient including an exit port, reservoir 21, threaded lead screw 40 coupled to the proximal end wall 41 of the reservoir 21. Element 41 serves as a removable end wall of the reservoir 21 because it establishes the end of the reservoir. (col. 10, ll. 7-28). The dispenser is run by a motor to rotate the lead screw, which in turn, advances the plunger 146 which has an interior insert 154. Whitney does not disclose the plunger threaded to the lead screw or insert. It would have been obvious to one of ordinary skill in the art at the time of the invention to thread the plunger to the end of the lead screw and to the insert because the use of threads to hold two elements in a fixed relationship is notoriously well-known in the mechanical arts.

Claims 1-3, 7, 8, 15, 18, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHOI ('423) in view of WILEY ('776) or PATALANO (US Patent No. 5,573,342). Choi discloses a device for delivering a fluid to a patient including a reservoir, threaded lead screw with plunger thereon which rotates with respect to the screw, but not a side wall of the reservoir, having a plunger insert 50,150, motor connected to the lead screw and a transcutaneous access tool connected to an exit port. (See figs. 1-3, 7, 8, 18, 20-22). Fig. 22 shows the insert and plunger made from different materials. Choi does not disclose the lead screw directly coupled to an end wall of the reservoir. Wiley (fig. 11) and Patalano (fig. 5) each teach coupling a lead screw directly to an end wall of reservoir in devices using lead screws to advance plungers in a

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reservoir to dispense fluids. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Wiley and Patalano in the device of Choi in order to provide better support for the lead screw to facilitate axial alignment of the lead screw with the plunger and reservoir so to make a more durable dispensing mechanism.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Response to Arguments

Applicant's arguments with respect to claims 1-3, 7, 8, 15, 18, and 23 have been considered but are moot in view of the new ground(s) of rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (571) 272-4977. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
29 June 2005



MICHAEL J. HAYES
PRIMARY EXAMINER